

## REMARKS/ARGUMENTS

In response to the Office Action mailed July 22, 2005, Applicants respond as follows. Applicants acknowledge and respectfully thank the Examiner for withdrawing the previous 35 U.S.C. §112 rejections regarding claims 1-26, 33 and 35-44. See Office Action mailed July 22, 2005 (“OA”), page 2.

Claims 1-26 and 33-44 are pending in the present application. Claims 27-32 have been cancelled. These claims have been cancelled without prejudice to, or disclaimer of, the subject matter thereof. Applicants reserve the right to file continuation applications directed to the subject matter of any claims cancelled or withdrawn for any reason. The present response amends claims 9-13, 21-26 and 34 and adds new claims 45-47. It is submitted that no new matter has been introduced by the present amendments or new claims, and entry of the same is respectfully requested. By these amendments, Applicant does not acquiesce to the propriety of any of the Examiner’s prior rejections and does not disclaim any subject matter to which Applicant is entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

### **I. Rejection of Claim 34 Under 35 U.S.C. §112**

Claim 34 has been rejected under 35 U.S.C. §112, first paragraph, “...because the specification, while being enabling for inhibiting or treating blood coagulation, does not reasonably provide enablement for preventing blood coagulation.” OA, page 2. Claim 34 has been amended to read, in part, “[a] method for inhibiting or treating preventing blood coagulation ....” Accordingly, claim 34 is believed to be definite and fully supported by the specification and, as a result, the present rejection should be reconsidered and withdrawn.

### **II. Rejection of Claims 1, 2, 5, and 23-26 Under 35 U.S.C. §102(b)**

Claims 1, 2, 5 and 23-26 have been rejected under 35 U.S.C. §102(b) as being anticipated by the Pulfer *et al.* reference (Incorporation of Nitric Oxide-Releasing Crosslinked Polyethyleneimine Microspheres Into Vascular Grafts; Journal of Biomedical Materials Research; Wiley, New York, NY, Vol. 37, No. 2, November 1997; pp 182-189). OA, page 3. More specifically, the Examiner states, in part, “[h]ighly cross-linked” and ‘extremely hydrophobic’ are relative terms that read of the cross-linked and hydrophobic polymer of the prior art. Pulfer discloses cross-linked and hydrophobic polymer.” [sic] *Id.*

In order to support an anticipation rejection under 35 U.S.C. §102(b), the Examiner must show that each and every element of the claimed invention is shown identically in a single reference. *In re Bond*, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990) citing *Diversitech Corp v. Century Steps, Inc.*, 7 U.S.P.Q.2d 1315, 1317 (Fed. Cir. 1988). The Pulfer *et al.* reference does not contain each and every element of the claimed invention as they presently appear.

Claim 1 of the present application defines a highly cross-linked, extremely hydrophobic nitric oxide-releasing biocompatible polydiazoniumdiolated polyamine-functionalized polymer. As described in the specification, regarding the highly cross-linked aspect, the specification states, in part:

The term "highly cross-linked" as used herein is consistent with its ordinary meaning as understood by persons skilled in the art of synthetic organic chemistry. Therefore, as used in the present invention, the term "highly cross-linked" is defined as a polymer substrate having an extensive network of primary chemical bonds linking the individual monomers together such that the polymer is essentially bound into a single molecule. This definition is not inconsistent with the general understanding of the "highly-cross-linked." For example, and not intended as a limitation, when divinylbenzene (DVB) is used to form the polymer beads of the present invention, the individual monomers of DVB become linked together (polymerized) by interactions between vinyl groups on neighboring DVB molecules. As the polymer chain grows additional polymerization reactions occur within the polymer chain resulting in a cross-linked matrix. The more extensive these additional interactions are, the more highly cross-linked the polymer becomes.

Specification, paragraph 48, pages 21-22. Regarding extremely hydrophobic substances, the specification states:

The extreme hydrophobicity of its divinylbenzene substituents prevents such a polymer from swelling when immersed in aqueous solutions such as physiological or bodily fluids. While not wishing to be bound by any particular theory, it is believed that in non- or poorly cross-linked diazeniumdiolated hydrophobic polymers of the type disclosed in the prior art and in the '919 patent, the intrusion of water and other protonating species into the interior of the polymer causes it to rapidly swell. As large hydrophilic channels are created, the protonation of sequestered diazeniumdiolate groups within the polymer is facilitated and there is a corresponding liberation of NO from the polymer.

Specification, paragraph 49, page 22. The Pulfer *et al.* reference does not disclose these characteristics of highly cross-linked and highly hydrophobic substances. Therefore, the

invention as presently claimed is novel and inventive over the prior art of record and the present rejection should be reconsidered and withdrawn.

### **III. Rejection of Claims 3, 4, 6-22 and 33-44 Under 35 U.S.C. §103**

Claims 3, 4, 6-22 and 33-44 have been rejected under 35 U.S.C. §103(a) as being unpatentable over the Pulfer *et al.* reference. OA, page 4. More specifically, the Examiner states, in part, “[h]ighly cross-linked” and ‘extremely hydrophobic’ are relative terms that read of the cross-linked and hydrophobic polymer of the prior art. Pulfer discloses cross-linked and hydrophobic polymer.” [sic] *Id.*

To maintain a proper rejection under 35 U.S.C. §103, the USPTO must meet four conditions to establish a *prima facie* case of obviousness. First, the USPTO must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the USPTO must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant’s disclosure. Third, the prior art must teach or suggest all of the claim limitations. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Fourth, if an obviousness rejection is based on some combination of prior art references, the USPTO must show the suggestion, teaching, or motivation to combine the prior art references. *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999).

Applicants agree with the Examiner that the phrases “highly cross-linked” and “extremely hydrophobic” are relative to the terms “cross-linked” and “hydrophobic.” That is to say that clearly a “highly cross-linked polymer” is more cross-linked than a “cross-linked polymer” and an “extremely hydrophobic polymer” is hydrophobic than a “hydrophobic polymer.” As admitted by the Examiner, the “Pulfer *et al.* reference discloses cross-linked and hydrophobic polymers.” The reference does not disclose a “highly cross-linked” and “extremely hydrophobic” polymer as described in paragraphs 48 and 49 of the present application. This disclosure would be required in order for the Examiner to make a §103 rejection with regard to this reference. Applicants submit that the Examiner has not established a *prima facie* case of obviousness for rejecting claims 3, 4, 6-22 and 33-44. Each of the claims within this claim set define unobvious patentable subject matter over the Pulfer *et al.* reference under 35 U.S.C. §103. Accordingly, the present rejection should be reconsidered and withdrawn.

#### **IV. Claim Objections and Notices**

The Examiner objected to claims 9-13 as being in improper form under 37 CFR 1.75(c). OA, page 4. Claims 9-13, as well as claims 21-26 have been amended into a proper claim format.

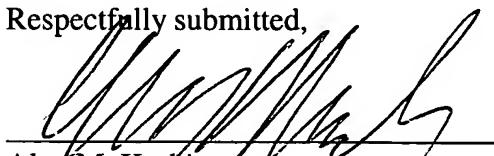
The Examiner next noted that paragraph [0013] refers to "the '666 patent" without a previous reference to this patent. The first reference to the '666 patent can be found in the specification at paragraph [0004], page 2.

#### **CONCLUSION**

Applicant has properly and fully addressed the Examiner's grounds for rejection. Applicant submits that the present application is now in condition for allowance. If the Examiner has any questions or believes further discussion will aid examination and advance prosecution of the application, a telephone call to the undersigned is invited.

The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5021.

Respectfully submitted,



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Alan M. Krubiner  
Registration No. 26,289  
Attorney for Applicant

Medtronic Vascular, Inc.  
3576 Unocal Place  
Santa Rosa, CA 95403  
Facsimile No.: (707) 543-5420